UNITED STATES DISTRICT COURT
NEW YORK

In re: MIRAPEX PRODUCTS LIABILITY LITIGATION

NANCY MARSHALL,

CIVIL NO.: 1:14-CV-992 (GLS/RFT)

Plaintiff,

-against-

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,
a Delaware corporation,
100 S. 5th Street, # 1075
Minneapolis, MN 55402

PFIZER, INC., a Delaware corporation,
c/o CT Corporation System, Inc.
100 S. 5th Street, # 1075
Minneapolis, MN 55402

PHARMACIA CORPORATION, a Delaware corporation,
100 S. 5th Street, # 1075
Minneapolis, MN 55402
and

PHARMACIA & UPJOHN COMPANY, LLC,
100 S. 5th Street, # 1075
Minneapolis, MN 55402

Defendants.

COMPLAINT AND DEMAND FOR JURY TRIAL

PLAINTIFF NANCY MARSHALL'S COMPLAINT

PLAINTIFF Nancy Marshall, as and for her causes of action against the above-named defendants, alleges and states on information and belief as follows:

PARTIES, JURISDICTION & VENUE

1. Plaintiff Nancy Marshall is a resident of Markelville, County of Madison, State of Indiana.

2. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer Ingelheim") or ("BIP"), is a foreign corporation duly licensed to do business in the State of New York.

3. Defendant Pfizer, Inc. ("Pfizer") is a foreign corporation duly licensed to do business in the State of New York..

4. Defendant Pharmacia Corporation ("Pharmacia") is a foreign corporation duly licensed to do business in the State of New York.

5. Defendant Pharmacia & Upjohn Company LLC ("Pharmacia & Upjohn") is a foreign limited liability company duly licensed to do business in the State of New York.

6. This court has subject matter jurisdiction pursuant to 28 U.S.§ 1332(a) because the amount in controversy exceeds $75,000, exclusive of interests and costs, and because no defendant named herein shares citizenship with the Plaintiff.

7. The defendants (Boehringer, Pfizer, Pharmacia and Pharmacia & Upjohn collectively) are subject to the *in personam* jurisdiction of this Court and the Northern Federal District of Indiana, and the venue is proper pursuant to 28 U.S.C. §1391 because the defendants did and/or do business within and have continuous and systematic contacts with New York, have consented to

jurisdiction in New yhork and/or committed a tort in the whole or in part in the State of New York and the Northern Federal District of Indiana against the Plaintiff, have advertised in both districts, received substantial compensation and profits from the sales of drugs in both districts, made material omissions and misrepresentations in both districts, violated state and federal statutes and/or regulations in both districts, and breached warranties in both districts.

FACTUAL BACKGROUND

A. DEFENDANTS HAVE AGGRESSIVELY MARKETED AND PROMOTED MIRAPEX WHILE DEFENDANTS' KNOWLEDGE OF ITS HARMFUL SIDE EFFECTS IS CONCEALED.

8. Defendants jointly created, developed, designed, researched, manufactured, tested, labeled, packaged, launched, supplied, marketed, sold, advertised, promoted, and distributed in interstate commerce the pharmaceutical pramipexole dihydrochloride under the brand name Mirapex. Mirapex is indicated for treatment of the signs and symptoms of idiopathic Parkinson's Disease and Restless Legs Syndrome, and Mirapex was promoted for treatment off label for fibromyalgia. On information and belief, Mirapex is promoted by defendants and/or commonly prescribed for treatment of other movement disorders, fibromyalgia, and depression in a joint enterprise.

9. Parkinson's Disease is a chronic progressive neurological disease caused by degeneration of brain cells that produce the chemical messenger dopamine. Parkinson's Disease is marked especially by tremor of resting muscles, rigidity, slowness of movement, impaired balance,

and a shuffling gait. RLS is also a neurological disorder believed to be caused by a dopamine imbalance in the brain. RLS is a condition in which one's limbs, particularly one's legs, feel extremely uncomfortable while sitting or lying down.

10. Mirapex is within the class of drugs known as dopamine agonists. Dopamine agonists directly stimulate dopamine receptors and mimic the action of dopamine in the brain.

11. There are at least five types of dopamine receptors in the brain, numbers D_1 to D_5. Dopamine agonists function by binding to these receptors. The function of any particular type of dopamine agonists is determined in part by its affinity or selectivity for particular receptors. Mirapex has the strongest affinity for D_3 dopamine receptors and also binds to the D_2 and D_4 receptors. The D_3 receptors are most highly concentrated in the brain's mesolimbic pathway, an area of the brain associated with pleasure, reward-seeking behavior and reinforcement systems.

12. In December 1995, Pharmacia & Upjohn submitted an Application to Market a New Drug ("NDA") to the United States Food and Drug Administration ("FDA"). The application was resubmitted in January 1997. The applications sought approval to market Mirapex tablets containing doses of 0.125 mg, 0.25 mg, 0.5 mg, 1.0 mg, 1.25 mg, and 1.5 mg for the treatment of the signs and symptoms of Parkinson's Disease (NDA 20-667). In July 1997, the FDA approved Mirapex for treating adults with Parkinson's Disease.

13. Defendants embarked upon a massive marketing and promotional campaign urging doctors to use Mirapex, but Defendants have never warned that Mirapex causes pathological gambling addictions and obsessive compulsive behaviors. Defendants have never sent out any "Dear Doctor" letters to inform doctors of this risk of Mirapex.

14. Defendants changed the Mirapex label or prescribing information in November 2004 to reflect post-marketing reports associating Mirapex with pathological gambling and other compulsive behaviors. Prior to this change, the Mirapex label made no mention of the link between compulsive behaviors, like pathological gambling, and Mirapex. The November 2004 label change added a short paragraph at the end of the ADVERSE REACTIONS section entitled "post-Marketing Experience" that noted that "compulsive behaviors (including sexual and pathological gambling)" have been identified as adverse reactions to Mirapex. In February 2006, Defendants added two short paragraphs in the PRECAUTIONS section of the Mirapex label or prescribing information entitled "Impulse-Control/Compulsive Behaviors" and "Information for Patients," respectively. These revisions state that "impulse control disorders/compulsive behaviors can occur" while taking Mirapex, including "pathological gambling." The revised label or prescribing information also states that Mirapex-related compulsive behaviors "are generally reversible upon dose reduction or treatment discontinuation." To date, there is no mention of compulsive behaviors in the WARNINGS section of the label or prescribing information.

15. Defendants had, or should have had, knowledge that Mirapex can cause compulsive behaviors like pathological gambling addictions long before the labeling changes of November 2004 and February 2006.

16. In August 2005, doctors from the Mayo Clinic published a report in the *Archives of Neurology* entitled "Pathological Gambling Caused by Drugs Used to Treat Parkinson's Disease." This study reported that eleven of the clinic's Parkinson's Disease patients, all of whom were on dopamine agonists, had recently developed pathological gambling addiction. Of the eleven, nine were taking Mirapex. For the eight patients with whom the doctors were able to follow up, all of these patients' gambling problems resolved after discontinuing the dopamine agonist. The Mayo doctors concluded that an association existed between pathological gambling and dopamine agonist therapy, that Mirapex was the agonist primarily implicated, and that this may be related to the disproportionate stimulation of the D3 dopamine receptor. The study concluded that dopamine agonists "appear to be *uniquely implicated* as a cause of pathological gambling and that disproportionate stimulation of dopamine receptors in the brain may be responsible."

17. Since the Mayo study was published, the lead author, Dr. M. Leeann Dodd, has stated that fourteen other Mayo Clinic patients have since been found to have the same problem. According to Dr. Dodd in the American Psychiatric Association publication *Psychiatric News*, affected patients are usually switched to different drugs or doses, and the result is often dramatic, "like a light switch being turned off when they stopped the drug."

18. In 2003, two years before the Mayo study, Dr. Mark Stacy and his colleagues at the Muhammad Ali Parkinson Research Center at the Barrow Neurological Institute in Phoenix published a study linking dopamine agonists with pathological gambling. In this retrospective database review of 1,884 Parkinson's patients, Dr. Stacy and his colleagues reported the correlation of Mirapex with pathological gambling. The authors found that the overall incidence of pathological gambling in their patients with Parkinson's was 0.05% regardless of therapy, but the incidence of pathological gambling for patients on Mirapex was 1.5%. The authors noted that their patients' excessive gambling seemed to begin with an increase in dopamine agonist therapy and resolve with dosage reduction. The authors concluded with a statement on the appropriateness of informing patients of a potential risk of pathological gambling while on dopaminergic therapy, especially Mirapex.

19. As of November 2004, the FDA's Adverse Event Reporting System contained 39 reports of Mirapex users with pathological gambling addiction. An analysis led by Dr. Ana Szarfman of the FDA and reprinted in the February *2006 Archives of Neurology* reported that this incidence of gambling is "380 times greater than expected."

20. Even when faced with evidence that showed Mirapex was causing compulsive behaviors like pathological gambling, and in the face of calls from the medical establishment to conduct further research and warn patients about this possible effect of Mirapex, Defendants have either failed to investigate or conduct any studies on the possible compulsive behavior side effects of Mirapex or have failed to make public the results of any studies or investigations that they might have done.

21. At all times, the Defendants themselves, or by and through the use of others, did manufacture, create, design, test, label, sterilize, distribute, supply, prescribe, market, sell, advertise, warn, and otherwise distribute in interstate commerce and in the State of Delaware, the pharmaceutical product known as Mirapex.

22. Mirapex has been linked to compulsive behavior leading to loss of income, loss of savings, loss of family contact, divorce, adultery, compulsive eating, compulsive gambling, compulsive sexual behavior, alienation of friends, alienation of family, loss of good name, loss of job, bankruptcy, loss of good credit, arrest, criminal convictions, suicide attempts, automobile accidents and even death.

23. Defendants' strategy has been to aggressively market and sell this product by minimizing the perception of risks and by failing to protect users form serious dangers which Defendants knew or should have known to result from use of this product.

24. Defendants widely and successfully marketed Mirapex in the United States to induce widespread use of the product. The marketing campaign consisted of direct-to-consumer advertisements, promotional literature to be placed in the offices of doctors and other healthcare providers and other promotional materials provided to potential Mirapex users.

25. The advertising program, as a whole, sought to create the image, impressions and belief in consumers and physicians that the use of Mirapex was safe for human use, had fewer side effects and adverse reactions than other methods for treating Parkinson's or

Restless Leg Syndrome even though the Defendants knew these facts to be false, and even though the Defendants had no reasonable grounds for believing them to be true.

26. Each Defendant purposefully downplayed and understated the health hazards and risks associated with Mirapex. The Defendants, through promotional literature, deceived potential users of Mirapex by relating positive information, and manipulating statistics to suggest widespread acceptability, while downplaying the known adverse and serious health effects. The Defendants concealed material relevant information from potential Mirapex users and thereby minimized the concern by user and prescriber regarding the safety of Mirapex.

27. In particular, in the materials published by the Defendants, they falsely misrepresented the severity, frequency, and nature of adverse health effects caused by Mirapex, and falsely represented that adequate testing had been conducted concerning Mirapex. As a result of the Defendants' advertising and marketing efforts, and their representations concerning the subject product, the drug was widely prescribed throughout the United States. The product warnings in effect during the period when Plaintiff took Mirapex were both substantively and graphically wholly inadequate to alert prescribing physicians and consumer patients about the dangers of the drug, including the obsessive behavior, compulsive behavior, and mental instability risks associated with this drug which was then known to the Defendants.

28. Prior to and following the date on which the aforementioned product was ingested by Plaintiff, Defendants knew that the product was unsafe and had the potential and propensity to produce serious and/or life-threatening/life-altering injuries and other damages. Notwithstanding the foregoing knowledge by the Defendants, at all times herein mentioned, the Defendants failed to take appropriate action to cure the nature of said defects or to adequately warn users of said product and their physicians of said dangerous characteristics and defects.

29. At all times herein mentioned, the Defendants have known that the subject drug product can cause serious and permanent physical injuries and they have failed to adequately disseminate this information to, or adequately warn, governmental agencies, physicians, drug recipients and/or the general public, and have continued to advise physicians and the general public that the drug is safe, thereby continuing their tortuous activities against Plaintiff from the date of ingestion to the present.

30. Had Plaintiff known about the number and type of adverse reactions associated with this drug, including increased obsessive behavior, compulsive behavior, mental instability, loss of income, loss of savings, loss of family contact, divorce, adultery, compulsive eating, compulsive gambling, compulsive sexual behavior, alienation of friends, alienation of family, loss of good name, loss of job, bankruptcy, loss of good credit, arrest and even death, Plaintiff would not have taken Mirapex.

31. Plaintiff avers that the Defendants actively encouraged and/or affirmatively failed to take effective steps to discourage aggressive dispensation of Mirapex.

32. Plaintiff has sustained and will continue to sustain injuries on a continuing basis, by virtue of the drug ingested, which have continued to cause injuries from the date of ingestion to the present.

33. The damages sustained by Plaintiff include but are not limited to special and general damages for pain and suffering, physical and emotional losses, as well as loss of credit, monetary damages, and medical and other bills and expenses.

34. Plaintiff further pleads that any and all limitations statutes applicable to these causes of action alleged herein are tolled by the delay in discovery of the injuries as Plaintiff did not discover, nor did she have a reason or a reasonable suspicion to discover a factual basis for her injuries until December of 2013. Moreover, Defendants' actions in concealing the true extent and nature of the injuries associated with Mirapex operate to toll statutes of limitation under principles of equitable tolling.

35. At all times herein mentioned, the Defendants: (i) knew that the aforementioned product was dangerous and unsafe for ingestion in the human system as previously delineated in this Complaint; (ii) concealed said dangers and health risks from Plaintiff's physicians, and the public in general; (iii) made misrepresentations to Plaintiff, her physicians, and the public in

general as previously delineated in this Complaint; and (iv) with full knowledge of the health risks associated with the aforementioned product and without adequate warnings of same, manufactured, and distributed said product for the use by Plaintiff and the public in general.

36. Prior to the manufacturing, sale and distribution of said drug product the Defendants knew that said drug product was in a defective condition as previously described, and knew that those who were prescribed and took the same would experience, and did experience, severe physical, mental, and emotional injuries,. Further, the Defendants, through their officers, directors and managing agents, had prior notice and knowledge from several sources, prior to the date of dispensing of said drug product to Plaintiff, that the drug presented a substantial and unreasonable risk of harm to the public, including Plaintiff, and as said consumers of said drug were unreasonably subjected to risk of injury, damages, or death from the consumption of said drug.

37. Despite such knowledge, the Defendants, acting through their officers, directors, and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in said drugs and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in said drug. The Defendants intentionally proceeded with the manufacturing, sale and distribution and marketing of said drug, knowing persons would be exposed to serious potential danger, in order to advance their own pecuniary interest.

B. UNAWARE OF THE TERRIBLE SIDE EFFECTS, PLAINTIFF FALLS PREY TO THE HARMFUL EFFECTS OF MIRAPEX.

38. Plaintiff Nancy Marshall was born on December 15, 1953 in London, Kentucky. Plaintiff graduated from Mount Vernon High School in Fortville, Indiana 46040 in 1972. Plaintiff completed Bryman School of Dentistry in 1973 as a Dental Assistant.

39. Plaintiff was married to Harlan Douglas Marshall on March 13, 2982. Plaintiff has two children, ages 38 and 30.

40. Plaintiff has been diagnosed with Restless Leg Syndrome. Between the years of 2004 and the present, Plaintiff has been prescribed Mirapex.

41. From 2004 through the present, the following doctor examined and prescribed Mirapex to Plaintiff: Lawrence Blankenship, M.D., Neurologist, 2101 Jackson Street, Suite 106, Anderson, Indiana 46016.

42. Plaintiff Marshall began to shop, spend and gamble compulsively and spent her income and savings after being prescribed and ingesting Mirapex.

43. As a result of Plaintiff's new compulsive behaviors, Plaintiff's personal life began to suffer. Moreover, Plaintiff's familial and social networks were directly impacted by Plaintiff's compulsive shopping, spending and gambling behaviors as both her and her husband's savings and retirement accounts vanished.

44. At no point did any of Plaintiff's treating physicians receive a warning letter or a "Dear Doctor" letter informing them about the dangerous link between Mirapex and excessive compulsive disorders including excessive gambling, spending and shopping.

45. Based on these facts, Plaintiff has suffered substantial monetary damages

FIRST CAUSE OF ACTION
Strict Liability – Design, Manufacturing and Warning – In Tort against all Defendants

46. Plaintiff incorporate by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

47. Defendants had a duty to provide adequate warnings and instructions for Mirapex to use reasonable care to design a product that is not unreasonably dangerous to users, and to adequately test their product.

48. The Mirapex manufactured and/or supplied to Plaintiff by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or supplier, it was in an unreasonably dangerous and defective condition for its intended use and posed a risk of serious compulsive behaviors and harm to Plaintiff and other consumers which could have been reduced or avoided, *inter alia,* by the adoption of a reasonable alternative design.

49. The Mirapex manufactured and/or supplied to Plaintiff by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or supplier, Mirapex had not been adequately tested, was in an unreasonably dangerous and defective condition, and posed a risk of serious compulsive behaviors and harm to Plaintiff and other consumers, and withdrawal effects related to DAWS.

50. The Mirapex manufactured and/or supplied to Plaintiff by Defendants was defective due to inadequate warnings or instructions because the Defendants knew or should have known through testing, scientific knowledge, advances in the field or otherwise, that the product created a risk of compulsive behaviors, injury, serious harm and withdrawal effects related to DAWS, and was unreasonably dangerous to Plaintiff and other consumers, about which Defendants failed to warn.

51. The Mirapex manufactured and/or supplied to Plaintiff by Defendants was defective, dangerous, and had inadequate warnings or instructions at the time it was sold, and Defendants thereafter acquired additional knowledge and information confirming the defective and dangerous nature of Mirapex. Despite this knowledge and information, Defendants failed and neglected to issue adequate warnings or post-sale warnings that Mirapex causes compulsive behaviors, especially pathological gambling addictions, including failure to warn about the severity and duration of such compulsive behaviors, and Defendants failed to warn of the withdrawal effects associated with DAWS. Defendants failed to provide adequate warnings to users, purchasers, or prescribers of Mirapex, including Plaintiff and her physicians, and instead continued to sell Mirapex in an unreasonably dangerous form without adequate warnings or instructions.

52. As a direct and proximate result of Defendants' conduct, including the inadequate warnings, lack of adequate testing, and the defective and dangerous nature of Mirapex, Plaintiff has suffered, and will continue to suffer physical injury, emotional distress, harm and economic loss as alleged herein.

SECOND CAUSE OF ACTION
Breach of Express Warranty by Defendants

53. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

54. Defendants expressly warranted to physicians and consumers, including Plaintiff and her physicians, that Mirapex was safe and/or well-tolerated.

55. Mirapex does not conform to these express representations because it is not safe and/or well-tolerated because it causes pathological gambling addictions that can lead to financial ruin, job loss, familial devastation and suicide attempts. Also, Mirapex does not conform to the Defendants ' representations that scientific studies had shown that Mirapex was safe and/or well-tolerated .

56. As a direct and proximate result of the breach of Defendants' warranties, Plaintiff suffers, and will continue to suffer physical injury, emotional distress, harm, and economic loss as alleged herein.

THIRD CAUSE OF ACTION
Breach of Implied Warranty

57. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

58. At the time Defendants marketed, sold, and distributed Mirapex, Defendants knew of the use for which Mirapex was intended and impliedly warranted Mirapex to be of merchantable quality, safe and fit for such use.

59. Defendants knew, or had reason to know, that Plaintiff and her physicians would rely on the Defendants' judgment and skill in providing Mirapex for its intended use.

60. Plaintiff and her physicians reasonably relied upon the skill and judgment of Defendants as to whether Mirapex was of merchantable quality, safe, and fit for its intended use.

61. Contrary to such implied warranty, Mirapex was not of merchantable quality or safe or fit for its intended use, because the product was, and is, unreasonably dangerous, defective and unfit for the ordinary purposes for which Mirapex was used.

62. As a direct and proximate result of the breach of implied warranty, Plaintiff suffered, and will continue to suffer physical injury, emotional distress, harm., and economic loss as alleged herein.

FOURTH CAUSE OF ACTION

Negligence

63. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

64. At all times material herein, Defendants had a duty to exercise reasonable care and the duty of an expert in all aspects of the design, formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, promotion, advertising, sale, warning and post-sale warning to assure the safety of the product when used as intended or in a way that Defendants could reasonably have anticipated, and to assure that the consuming public, including the Plaintiff and her physicians, obtained accurate information and adequate instructions for the safe use or non-use of Mirapex. Defendants had a duty to

warn Plaintiff, her physicians, and the public in general of Mirapex's dangers and serious side effects, including serious compulsive behaviors like pathological gambling addictions, since it was reasonably foreseeable that an injury could occur because of Mirapex's use.

65. At all times material herein, Defendants failed to exercise reasonable care and the duty of an expert and knew, or in the exercise of reasonable care should have known, that Mirapex was not properly manufactured, designed, compounded, tested, inspected, packaged, labeled, warned about, distributed, marketed, advertised, formulated, promoted, examined, maintained, sold and/or prepared.

66. Each of the following acts and omissions herein alleged was negligently and carelessly performed by Defendants, resulting in a breach of the duties set forth above. These acts and omissions include, but are not restricted to, negligence and careless research and testing of Mirapex; negligent and careless design or formulation of Mirapex; negligent and careless failure to give adequate warnings that would attract the attention of Plaintiff, her physicians, and the public in general of the potentially dangerous, defective, unsafe, and deleterious propensity of Mirapex and of the risks associated with its use; negligent and careless failure to provide instructions on ways to safely use Mirapex to avoid injury; negligent and careless failure to explain the mechanism, mode, and types of adverse events associated with Mirapex; negligent representations that Mirapex was safe and/or well-tolerated; and negligent and careless failure to issue adequate post-sale warnings that Mirapex causes an increased risk of compulsive behaviors, including pathological gambling.

67. As a direct and proximate result of Defendants' negligence, Plaintiff suffered, and will continue to suffer physical injury, emotional distress, harm, and economic loss as alleged herein.

FIFTH CAUSE OF ACTION
Negligence Per Se
Violation of 21 U.S.C. §§ 331, 352 and 21 C.F.R. §§ 201.56, 201.57, 202.1

68. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

69. At all times herein mentioned, Defendants had an obligation not to violate the law, including the Federal Food, Drug, and Cosmetic Act and the applicable regulations, in the manufacture, design, formulation, compounding, testing, production, processing, assembling, inspection, research, promotion, advertising, distribution, marketing, promotion, labeling, packaging, preparation for use, consulting, sale, warning, and post- sale warning of the risks and dangers of Mirapex.

70. By reason of its conduct as alleged herein, Defendants violated provisions of statutes and regulations, including, but not limited to, the following:

a. Defendants violated the Federal Food, Drug and Cosmetic Act, U.S.C. §§ 331 and 352, by misbranding Mirapex;

b. Defendants failed to follow the "[g]eneral requirements on content and format of labeling for human prescription drugs" in violation of 21 C.F.R. §§ 201.56;

c. Defendants failed to follow the "[s]pecific requirements on content and format of labeling for human prescription drugs" in violation of 21 C.F.R. §§ 201.57;

d. Defendants advertised and promoted Mirapex in violation of 21 C.F.R. §202.1.

These statutes and regulations impose a standard of conduct designed to protect consumers of drugs, including Plaintiff. Defendants' violations of these statutes and regulations constitute negligence *per se*.

71. As a direct and proximate result of Defendants' statutory and regulatory violations, Plaintiff, a member of the class of persons protected by the above-mentioned statutes, suffered, and will continue to suffer physical injury, emotional distress, harm, and economic loss as alleged herein.

SIXTH CAUSE OF ACTION
Negligent Misrepresentation

72. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

73. Defendants misrepresented to consumers and physicians, including Plaintiff and her physicians and the public in general, that Mirapex was safe and/or well-tolerated when used as instructed when, in fact, Defendants knew or should have known that Mirapex was dangerous to the well-being of patients. Specifically, Defendants knew or should have known of and/or possessed evidence that Mirapex caused compulsive behaviors, and yet Defendants negligently misrepresented that there was no such evidence that Mirapex caused compulsive behaviors.

74. In 2004 and 2005, after the media began to publicize reports of Mirapex patients developing compulsive behaviors, including gambling addictions, Defendants made numerous false and misleading public misrepresentations denying the existence of any scientific evidence of a causal relationship between Mirapex and compulsive behaviors. Defendants made these false and misleading public misrepresentations denying the existence of any scientific evidence that Mirapex caused compulsive behavior through PR statements to media organizations, including, but not limited to, television news stations, television programs, newspapers, and news organizations such as the Associated Press.

75. Instances of Defendants' public misrepresentations denying the existence of any scientific evidence of a causal link between Mirapex and compulsive behavior include, but are not limited to: 1) a statement by Defendant BIPI submitted to and broadcast on the nationally broadcast Good Morning America television program on or about December 23, 2004; 2) statements by Defendant BIPI submitted to and publicized by the Associated Press, in major newspapers including but not limited to the New York Times, the Wall Street Journal, the Boston Globe, the Chicago Tribune, the Minneapolis Star Tribune, and on websites including but not limited to http://www.boston.com, http://www.MSNBC.com , http:/my.webmd.com, and http://health.dailynewscentral.com, on or about July 11 and 12, 2005; 3) a statement by Defendant BIPI submitted to and broadcast on NBC News in Baltimore on February 10, 2005. Many of these statements were made by BIPI

submitted to and broadcast on NBC News in Baltimore on February 10, 2005. Many of these statements were made by BIPI Public Relations Director Katherine King O'Connor. In these public statements, Defendants expressly denied having any scientific evidence that Mirapex caused compulsive behaviors.

76. Defendant BIPI also phrased the label submitted to the FDA in November 2004 in such a way as to downplay the evidence of a causal relationship, by stating that "[b]ecause these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure." Defendants also used an "Objection Handler," by which Defendants' agents distracted physicians from concerns about compulsive behavior, "Neutralized" those concerns and led them to believe that any problems with compulsive behavior were off-set by benefits offered by Mirapex.

77. Defendants also made public misrepresentations about whether compulsive behaviors were reported during the clinical trials of Mirapex. These statements denying any incidents of compulsive behavior in the clinical trials of Mirapex include, but were not limited to: 1) a statement made by BIPI Public Relations Director Katherine King O'Connor to WebMD and published on http://my.webmd.com on July 12, 2005 stating that Defendants did not see any cases of compulsive behavior during the clinical development of Mirapex; 2) a statement by Kirk Shepard on November 30, 2004, on CBS News in Cedar Rapids, Iowa, stating that "In the trials where we determined the safety and effectiveness of the drug there were no cases of compulsive behavior."

78. Defendants worked in concert to craft these public misrepresentations denying the existence of any evidence that Mirapex causes compulsive behaviors, and the misrepresentations were made on behalf of all Defendants. Defendants communicated via email, over the telephone, and through face-to-face meetings to collaborate on and agree upon the aforesaid public misrepresentations. Defendants made the aforesaid representations in the course of Defendants' business as designers, manufacturers, and distributors of Mirapex despite having no reasonable basis for their assertion that these representations were true and/or without having accurate or sufficient information concerning the aforesaid representations. Defendants were aware that without such information they could not accurately make the aforesaid representations.

79. At the time Defendants made the aforesaid misrepresentations, they did not have adequate proof upon which to base such representations, and in fact, given Defendants' knowledge about the pharmacology of Mirapex and the adverse events reported to Defendants, knew or should have known that these representations were false. At the time Defendants made the aforesaid representations denying any evidence that Mirapex caused compulsive behaviors, Defendants had significant knowledge of Mirapex's pharmacological properties, and had deliberately developed Mirapex to activate the brain's pathway that is involved in motivation and reward. In addition, Defendants had evidence indicating that the drug did cause compulsive behaviors, for example:

(a) Defendant's own early investigations of the pharmacological properties of Mirapex, as summarized in Defendants' Investigational New Drug Applications filed in 1990 and 1994, indicated that Mirapex targets D3 receptors in the mesolimbic system and that the mesolimbic pathways are involved in motivation and reward, and that animals receiving high doses of Mirapex developed behaviors such as compulsive gnawing;

(b) Defendants received many reports of serious gambling and other compulsive behaviors among patients in the Mirapex clinical trials in the mid-to late-1990's. At least eleven Mirapex clinical trial patients developed compulsive behaviors while on the drug, including at least five clinical trial patients who developed gambling addictions;

(c) Defendants had knowledge of an abstract presented in June 2000 by Drs. Samanta and Stacy at the Sixth International Congress of Parkinson's Disease and Movement Disorders in Barcelona, Spain entitled *Compulsive Gambling with Dopaminergic Therapy in Parkinson's Disease*, which reported that eight PD patients developed compulsive gambling after taking dopaminergic drugs, including Mirapex;

(d) In 2002, 2003, and 2004, Defendants received many post-marketing reports of Mirapex patients developing compulsive gambling;

(e) Defendants had knowledge of the September 2004 Clinical Expert Statement issued by doctors from BI Germany, which concluded that data about gambling and Mirapex "strongly suggest a pharmacodynamic effect of prarnipexole on pathological gambling" and that pathological gambling should be listed as a side effect of Pramipexole/Mirapex. Defendants' internal emails indicate that they were not surprised by this Clinical Expert statement, as it fit with Defendants' own knowledge and understanding of Mirapex's pharmacology and its effect on the brain;

(f) Defendants knew that BI Germany changed the Basic Product Information sheet (BPI) in August 2004 to list pathological gambling as a side effect of Mirapex, because BI Germany believed that sufficient evidence for a causal association existed; and

(g) When Defendants began to publicize statements denying that they had any evidence of causation, ne of the doctors from BI Germany emailed key decision-makers at Defendant BIPI expressing concern about these public statements denying evidence of causation, and reminded them that their doctors had concluded in the Clinical Expert Statement that evidence indicated a causal relationship existed.

80. Defendants failed to exercise reasonably care and competence in obtaining and/or communicating information regarding the dangerous side effects of Mirapex and otherwise failed to exercise reasonable care in transmitting this information to the Plaintiff, her physicians and the public in general.

81. Defendants' motive for covering up their knowledge of that fact that Mirapex caused compulsive behaviors was financial gain. Defendants weighed the impact of a gambling warning upon sales of Mirapex. For example, one document concludes that a "Compulsivity Label Change" would have a "Negative Impact on Mirapex Share and Growth" and represents a "Potential Deviation" from an "incremental sales/expenses" line that trended upward. Similarly, Defendants in another document compared the prevalence of compulsive side-effects at particular doses where Mirapex sales were greatest:

> [T]otal dose of 1.5 mg/day [and] below you don't see ob/comp behavior or sudden onset of sleep. This is low dose for monotherapy but effective dose for adjunct therapy where we get most of our business.

82. Defendants' fraudulent conduct also included manipulating the medical literature. Defendants shaped the medical literature about Mirapex, such that the literature cannot accurately reflect Mirapex's dangers. According to the Standard Operating Procedure governing publications, Boehringer entities were required to develop a "publication strategy" for each project. The purpose of this strategy was not to disseminate important data to the medical community, but to "generate a consistent image of the drug." To this goal, Boehringer shaped the medical literature in order to 1) serve marketing needs of showing effectiveness and 2) downplay dangers of the drug. Boehringer's policy was to ghost write draft publications which later surfaced as supposed objective medical literature. Alarmingly, Boehringer hired a group to draft articles. Articles were also drafted or outlined

by a public relations firm, often before a medical author was even identified. The articles were then sent to the "client," either "Pfizer medical" or "BI medical and mktg" who made changes. Only then were the articles sent to the person whom would ultimately be listed as the author.

83. Defendants manipulated literature on the very issues in this case. One publication considered by Boehringer' s Mirapex Publication Strategy was an article on "gambling" by a doctor who was once head of the Parkinson's Disease Foundation. The Publication Strategy establishes that in a "Pub Plan Meeting [publication planning meeting] held on June 8, 2004, Boehringer "agreed to offer assistance" to the doctor. The reason for BI's willingness to assist was very self-serving, and undercuts the objectivity of any ultimate article: "BI agreed to offer assistance in development [of the article on gambling] **to manage message.**"

84. Defendants also exercised veto and editing powers by restricting researchers' ability to publish data without prior approval. The question of whether data developed in clinical trials would be published was controlled by Defendants:

> Prior to publication of any results pertaining to the clinical trial, the investigator must submit a copy of the manuscript, abstract, etc. to the medical monitor who will circulate the materials for review and approval according to the Upjohn Manuscript/Abstract Publication Approval Process.

85. When negative data about Mirapex was published, such as the Mayo Clinic study showing that agonists (and in 9 of 11 cases, Mirapex) were "uniquely implicated" as a cause of pathological gambling, Defendants' consultants immediately challenged the data. On

the other hand,when data seemed positive from Defendants' point of view, Defendants would facilitate its publication. For example, in May 2004, Defendants reviewed a doctor's advance manuscript regarding depression and treatment with dopamine agonists in Parkinson's disease patients. The doctor reflected his understanding that the Defendants would help with publicity and further development of the research: "I am sending you the article that has been written . . . .If the article is accepted then we can discuss how best to publicize it . . . .[A]n option would be to expand the article into a book[.]"

86. Defendants' willingness to help publish selected data apparently led to editing powers over what was portrayed as objective data. The doctor's abstract discussing "Gambling, Sex and Parkinson's Disease." was sent to both Pfizer and Boehringer scientists with the alarming instructions to "please feel free to make any changes." Similarly, Defendants inserted their own conclusions into the medical literature, editing manuscripts of the CALM-PD data prior to its publication, and then wrongfully portrayed those conclusions in promotional pieces as objective scientific conclusions by medical scientists.

87. Defendants also fraudulently concealed and minimized, in their meetings with physicians, the fact that Mirapex causes compulsive behaviors. Defendants used purportedly positive data about Mirapex to deflect physicians' concerns about compulsive behaviors. The "Mirapex Objection Handler" instructs sales representatives who are asked about compulsive

behavior side-effects to "Neutralize" the concern with a method called "Influence with off-setting benefit" by pointing to purportedly positive data. This positive data, however, was not objective science.

88. At the time the aforesaid representations were made, Defendants intended to induce Plaintiff and her physicians to rely upon such representations. Defendants knew that if known information about compulsivity was shared with physicians and patients, there would be a "negative impact on Mirapex share and growth."

89. At the time the aforesaid representations were made by Defendants and at the time Plaintiff received Mirapex, Plaintiff and her physicians, and the public in general reasonably believed them to be true. At the time that Plaintiff received Mirapex, Defendants failed to inform Plaintiff or her treating physicians, Dr. Blankenship that Mirapex caused compulsive behavior, including compulsive shopping, spending and gambling, despite Defendants being in possession of such evidence. Plaintiff received no warnings, either written or oral that Mirapex caused obsessive compulsion behavior, including compulsive gambling, shopping, spending, and relied on these omissions.

90. Defendant Pfizer sales representatives were trained and advised when asked about compulsive behavior side-effects to "Neutralize" the concern and providing data that was not based on objective science.

91. In reasonable and justified reliance upon Defendants' representations and wrongful omissions, Plaintiff and her treating physicians Dr. Blankenship were induced to and did purchase and ingest Mirapex, and Plaintiff was induced to remain on Mirapex. If Plaintiff had known the

truth about the risks of using Mirapex, in particular that it could cause compulsive behaviors, Plaintiff either would not have taken their drug or if she had taken the drug, would have been on notice at the time that her compulsions manifested themselves that the drug was causally involved and would have stopped taking the drug.

92. As a direct and proximate result of reliance upon Defendants' misrepresentations, Plaintiff has suffered, and will continue to suffer physical injury, emotional distress, harm, and economic loss as alleged herein.

SEVENTH CAUSE OF ACTION
Fraudulent Misrepresentation

93. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

94. Defendants misrepresented to consumers and physicians, including Plaintiff and her physicians and the public in general, that Mirapex was safe and/or well-tolerated when used as instructed when, in fact, Defendants knew that Mirapex was dangerous to the well-being of patients. Specifically, Defendants knew of and/or possessed evidence that Mirapex caused compulsive behaviors, and yet Defendants fraudulently misrepresented that there was no such evidence that Mirapex caused compulsive behaviors.

95. In 2004 and 2005, after the media began to publicize reports of Mirapex patients developing compulsive behaviors, including gambling addictions, Defendants made numerous

false and misleading public misrepresentations denying the existence of any scientific evidence of a causal relationship between Mirapex and compulsive behaviors. Defendants made these false and misleading public misrepresentations denying the existence of any scientific evidence that Mirapex caused compulsive behavior through PR statements to media organizations, including, but not limited to, television news stations, television programs, newspapers, and news organizations such as the Associated Press.

96. Instances of Defendants' public misrepresentations denying the existence of any scientific evidence of a causal link between Mirapex and compulsive behavior include, but are not limited to: 1) a statement by Defendant BIPI submitted to and broadcast on the nationally broadcast Good Morning America television program on or about December 23, 2004; 2) statements by Defendant BIPI submitted to and publicized by the Associated Press, in major newspapers including but not limited to the New York Times, the Wall Street Journal, the Boston Globe, the Chicago Tribune, the Minneapolis Star Tribune, and on websites including but not limited to http://www.boston.com, http://www.MSNBC.com, http://my.webmd.com, and http://health.dailynewscentral.com, on or about July 11 and 12, 2005; 3) a statement by Defendant BIPI submitted to and broadcast on NBC News in Baltimore on February 10, 2005. Many of these statements were made by BIPI Public Relations Director Katherine King O'Connor. In these public statements, Defendants expressly denied having any scientific evidence that Mirapex caused compulsive behaviors.

97. Defendant BIPI also phrased the label submitted to the FDA in November 2004 in such a way as to downplay the evidence of a causal relationship, by stating that "[b]ecause these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure." Defendants also used an "Objection Handler," by which Defendants' agents distracted physicians from concerns about compulsive behavior, "Neutralized" those concerns and led them to believe that any problems with compulsive behavior were off-set by benefits offered by Mirapex.

98. Defendants also made public misrepresentations about whether compulsive behaviors were reported during the clinical trials of Mirapex. These statements denying any incidents of compulsive behavior in the clinical trials of Mirapex include, but were not limited to: I) a statement made by BIPI Public Relations Director Katherine King O'Connor to WebMD and published on http://my.webmd.com on July 12, 2005, stating that Defendants did not see any cases of compulsive behavior during the clinical development of Mirapex; 2) a statement by Kirk Shepard on November 30, 2004, on CBS News in Cedar Rapids, Iowa, stating that "In the trials where we determined the safety and effectiveness of the drug there were no cases of compulsive behavior."

99. Defendants worked in concert to craft these public misrepresentations denying the existence of any evidence that Mirapex causes compulsive behaviors, and the

misrepresentations were made on behalf of all Defendants. Defendants communicated via email, over the telephone, and through face-to-face meetings to collaborate on and agree upon the aforesaid public misrepresentations. Defendants made the aforesaid representations in the course of Defendants' business as designers, manufacturers, and distributors of Mirapex despite having no reasonable basis for their assertion that these representations were true and/or without having accurate or sufficient information concerning the aforesaid representations. Defendants were aware that without such information they could not accurately make the aforesaid representations.

100. At the time Defendants made the aforesaid representations, they did not have adequate proof upon which to base such representations, and in fact, given Defendants" knowledge about the pharmacology of Mirapex and the adverse events reported to Defendants, knew or should have known that these representations were false. At the time Defendants made the aforesaid representations denying any evidence that Mirapex caused compulsive behaviors, Defendants had significant knowledge of Mirapex's pharmacological properties, and had deliberately developed Mirapex to activate the brain's pathway that is involved in motivation and reward. In addition, Defendants had evidence indicating that the drug did cause compulsive behaviors, for example:

a. Defendants' own early investigations of the pharmacological properties of Mirapex, as summarized in Defendants' Investigational New Drug Applications filed in 1990 and 1994, indicated that Mirapex targets DJ receptors in the mesolimbic system and that the mesolimbic pathways are involved in motivation and reward, and that animals receiving high doses of Mirapex developed behaviors such as compulsive gnawing;

b. Defendants received many reports of serious gambling and other compulsive behaviors among patients in the Mirapex clinical trials in the mid- to late-1990s. At least eleven Mirapex clinical trial patients developed compulsive behaviors while on the drug, including at least five clinical trial patients who developed gambling addictions;

c. Defendants had knowledge of an abstract presented in June 2000 by Drs. Samanta and Stacy at the Sixth International Congress of Parkinson's Disease and Movement Disorders in Barcelona, Spain entitled *Compulsive Gambling with Dopaminergic Therapy in Parkinson's Disease,* which reported that eight PD patients developed compulsive gambling after taking dopaminergic drugs, including Mirapex;

d. In 2002, 2003, and 2004, Defendants received many post-marketing reports of Mirapex patients developing compulsive gambling.

e. Defendants had knowledge of the September 2004 Clinical Expert Statement issued by doctors from BI Gennany, which concluded that data about gambling and Mirapex "strongly suggest a pharmacodynamic effect of pramipexole on pathological gambling" and that pathological gambling should be listed as a side effect of Pramipexole/Mirapex. Defendants' internal emails indicate that they were not surprised by this Clinical Expert statement, as it fit with Defendants' own knowledge and understanding of Mirapex' s pharmacology and its effect on the brain;

f. Defendants knew that Bl Germany changed the Basic Product Information sheet (BPI) in August 2004 to list pathological gambling as a side effect of Mirapex, because BI Germany believed that sufficient evidence for a causal association existed; and

g. When Defendants began to publicize statements denying they had any evidence o f causation, one of the doctors from BI Germany emailed key decision-makers at Defendant BIPI expressing concern about these public statements denying evidence of causation, and reminded them that their doctors had concluded in the Clinical Expert Statement that evidence indicated a causal relationship existed.

101. Defendants' motive for covering up their knowledge of that fact that Mirapex caused compulsive behaviors was financial gain. Defendants weighed the impact of a gambling warning upon sales of Mirapex. For example, one document concludes that a "Compulsivity Label Change" would have a "Negative Impact on Mirapex Share and Growth" and represents a "Potential Deviation" from an "incremental sales/expenses" line that trended upward. Similarly, Defendants in another document compared the prevalence of compulsive side-effects at particular doses where Mirapex sales were greatest:

> [T]otal dose of 1.5 mg/day [and] below you don't see ob/comp behavior or sudden onset of sleep. This is low dose for monotherapy but effective dose for adjunct therapy where we get most of our business.

102. Defendants' fraudulent conduct also included manipulating the medical literature. Defendants shaped the medical literature about Mirapex, such that the literature cannot accurately reflect Mirapex's dangers. According to the Standard Operating Procedure governing publications, Boehringer entities were required to develop a "publication strategy" for each project. The purpose of this strategy was not to disseminate important data to the medical community, but to "generate a consistent image of the drug." To this goal, Boehringer shaped the medical literature in order to 1) serve marketing needs of showing effectiveness and 2) downplay dangers of the drug. Boehringer' s policy was to ghost write draft publications which later surfaced as supposed objective medical literature. Alarmingly, Boehringer hired a group to draft articles. Articles were also drafted or outlined by a public relations firm, often before a medical author was even

identified. The articles were then sent to the "client," either "Pfizer medical" or "BI medical and mktg" who made changes. Only then were the articles sent to the person whom would ultimately be listed as the author.

103. Defendants manipulated literature on the very issues in this case. One publication considered by Boehringer's Mirapex Publication Strategy was an article on "gambling" by a doctor who was once head of the Parkinson's Disease Foundation. The Publication Strategy establishes that in a "Pub Plan Meeting [publication planning meeting] held on June 8, 2004, Boehringer "agreed to offer assistance" to the doctor. The reason for BI's willingness to assist was very self-serving, and undercuts the objectivity of any ultimate article: "BI agreed to offer assistance in development [of the article on gambling] **to manage message.**"

104. Defendants also exercised veto and editing powers by restricting research ability to publish data without prior approval. The question of whether data developed in clinical trials would be published was controlled by Defendants:

> Prior to publication of any results pertaining to the clinical trial, the investigator must submit a copy of the manuscript, abstract, etc. to the medical monitor who will circulate the materials for review and approval according to the Upjohn Manuscript/ Abstract Publication Approval Process.

105. When negative data about Mirapex was published, such as the Mayo Clinic study showing that agonists (and in 9 of 11 cases, Mirapex) were "uniquely implicated" as a cause of pathological gambling, Defendant's consultants immediately challenged the data. On the other hand,

when data seemed positive from Defendants' point of view, Defendants would facilitate its publication. For example, in May 2004, Defendants reviewed a doctor's advance manuscript regarding depression and treatment with dopamine agonists in Parkinson disease patients. The doctor reflected his understanding that the Defendants would help with publicity and further development of the research: "I am sending you the article that has been written . . . If the article is accepted then we can discuss how best to publicize it . . . . [A]n option would be to expand the article into a book[.]"

106. Defendants' willingness to help publish selected data apparently led to editing powers over what was portrayed as objective data. The doctor's abstract discussing "Gambling, Sex and Parkinson's Disease," was sent to both Pfizer and Boehringer scientists with the alarming instructions to "please feel free to make any changes." Similarly, Defendants inserted their own conclusions into the medical literature, editing manuscripts of the CALM-PD data prior to its publication, and then wrongfully portrayed those conclusions in promotional pieces as objective scientific conclusions by medical scientists.

107. Defendants also fraudulently concealed and minimized, in their meetings with physicians, the fact that Mirapex causes compulsive behaviors. Defendants used purportedly positive data about Mirapex to deflect physicians' concerns about compulsive behaviors. The "Mirapex Objection Handler" instructs sales representatives who are asked about compulsive behavior side-effects to "Neutralize" the concern with a method called "Influence with off-setting benefit" by pointing to purportedly positive data. This positive data, however, was not objective science.

108. At the time the aforesaid representations were made, Defendants intended to induce Plaintiff and her physicians to rely upon such representations. Defendants knew that if known information about compulsivity was shared with physicians and patients, there would be a "negative impact on Mirapex share and growth".

109. At the time the aforesaid representations were made by Defendants and at the time Plaintiff received Mirapex, Plaintiff and her physicians, and the public in general reasonably believed them to be true. At the time that Plaintiff received, Defendants failed to inform Plaintiff or her prescribing physician, Larry Blankenship, M.D., that Mirapex caused compulsive behavior, including compulsive shopping, spending and gambling, despite Defendants being in possession of such evidence. Plaintiff received no warnings, either written or oral that Mirapex caused obsessive compulsion behavior, including compulsive shopping, spending and gambling, and relied on these omissions.

110. Defendant Pfizer sales representatives were trained and advised when asked about compulsive behavior side-effects to "Neutralize" the concern and providing data that was not based on objective science.

111. In reasonable and justified reliance upon Defendants' representations and wrongful omissions, Plaintiff and her treating physicians Dr. Blankenship were induced to and did purchase and ingest Mirapex, and Plaintiff was induced to remain on Mirapex. If Plaintiff had known the truth about the risks of using Mirapex, in particular that it could cause compulsive behaviors, Plaintiff either would not have taken their drug or if she had taken the drug, would

have been on notice at the time that her compulsions manifested themselves that the drug was causally involved and would have stopped taking the drug.

112. As a direct and proximate result of reliance upon Defendants' misrepresentations, Plaintiff has suffered, and will continue to suffer physical injury, emotional distress, harm, and economic loss as alleged herein.

EIGHTH CAUSE OF ACTION
Fraudulent Concealment

113. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

114. Defendants failed to disclose and in fact concealed and suppressed material and substantial facts to consumers and physicians, including Plaintiff and , physicians and the public in general, about the dangerousness of Mirapex, including Mirapex's impact on the brain's addiction pathways. Defendants concealed information about the risks of Mirapex when making the fraudulent statements detailed about, as well as generally failing to inform Plaintiff, physicians, and the public of the known risks of Mirapex. Defendants also used an "Objection Handler," during a time period including but not limited to May through September of 2005, to distract physicians from concerns about compulsive behavior and lead them to believe that any problems with compulsive behavior are off-set by benefits offered by Mirapex.

115. The fact that Defendants knew or should have known that Mirapex causes compulsive or addictive behaviors and acted to conceal this information from the public, physicians, and Plaintiff was also clear from decisions by Upjohn and BI to withhold samples of Mirapex from researchers who might implicate Mirapex in addictive behavior, including: 1) a decision by Upjohn/BI Development Team in February 1994 not to give samples of Mirapex to the National Institute on Drug Abuse; 2) a decision by representatives of Upjohn and BI in February 2004 not to give samples of Mirapex to a researcher named Torben Kling-Petersen who planned to use the samples in studies of intracranial self-stimulation. The fact that Defendants knew or should have known that Mirapex causes compulsive or addictive behaviors and acted to conceal this information from the public, physicians, and Plaintiff was also made clear by a decision in April 1995 by BI, which was also communicated to Upjohn, to block a researcher named Kjell Svensson from publishing a proposed abstract that discussed Mirapex and addiction.

116. At the time Defendants promoted Mirapex as safe and/or well-tolerated, they in fact knew that Mirapex was dangerous to the well-being of Plaintiff and others, based on the pharmacology of Mirapex and adverse events reported to Defendants. Defendants knew that Mirapex caused compulsive behaviors and knew of Mirapex's impact on the brain's addiction pathways when they represented that Mirapex did not cause compulsive behaviors and concealed material facts about Mirapex and addiction despite their duty to provide accurate warnings and information to Plaintiff, other consumers, and physicians, and provide information to Plaintiff, other consumers, and physicians as needed to clarify their other public statements and ensure that their representations regarding safety were not misleading.

117. Defendants worked in concert to conceal material information about the dangerousness of Mirapex, including Mirapex's impact on the brain's addiction pathways. Defendants made the aforesaid representations and/or concealments in the course of Defendants' business as designers, manufacturers, and distributors of Mirapex despite knowing that those representations were false and/or that their concealments involved material and substantial facts about the dangerousness of Mirapex. At the time Defendants made the aforesaid representations and/or concealments about the dangerousness of Mirapex, including Mirapex's impact on the brain's addiction pathways, Defendants had significant knowledge of Mirapex's pharmacological properties, and had deliberately developed Mirapex to activate the brain's pathway that is involved in motivation and reward. In addition, Defendants had the evidence indicating that the drug did cause compulsive behaviors, for example:

> A. Defendants' own early investigations of the pharmacological properties of Mirapex, as summarized in Defendants' Investigational New Drug Applications filed in 1990 and 1994, indicated that Mirapex targets D3 receptors in the mesolimbic system and that the mesolimbic pathways are involved in motivation and reward, and that animals receiving high doses of Mirapex developed behaviors such as compulsive gnawing;
>
> B. Defendants received many reports of serious gambling and other compulsive behaviors among patients in the Mirapex clinical trials in the mid- to late-1990s. At least eleven Mirapex clinical trial patients developed compulsive behaviors while on the drug, including at least five clinical trial patients who developed gambling addictions;
>
> C. Defendants had knowledge of an abstract presented in June 200 by Drs. Samanta and Stacy at the Sixth International Congress of Parkinson's Disease and Movement Disorders in Barcelona, Spain entitled *Compulsive Gambling with Dopaminergic Therapy in Parkinson's Disease*, which reported that eight PD patients developed compulsive gambling after taking dopaminergic drugs, including Mirapex;

> D. In 2002, 2003, and 2004, Defendants received many post-marketing reports of Mirapex patients developing compulsive gambling;
>
> E. Defendants had knowledge of the September 2004 Clinical Expert Statement issued by doctors from BI Germany, which concluded that data about gambling and Mirapex "strongly suggest a pharmacodynamic effect of pramipexole on pathological gambling" and that pathological gambling should be listed as a side effect of Prarnipexole/Mirapex. Defendants' internal emails indicate that they were not surprised by this Clinical Expert statement, as it fit with Defendants' own knowledge and understanding of Mirapex's pharmacology and its effect on the brain;
>
> F. Defendants knew that BI Germany changed the Basic Product Information sheet (BPI) in August 2004 to list pathological gambling as a side effect of Mirapex, because BI Germany believed that sufficient evidence for a causal association existed; and
>
> G. When Defendants began to publicize statements denying they had any evidence of causation, one of the doctors from BI Germany emailed key decision-makers at Defendant BIPI expressing concern about these public statements denying evidence of causation, and reminded them that their doctors had concluded in the Clinical Expert Statement that evidence indicated a causal relationship existed.

118. Defendants' motive for covering up their knowledge of that fact that Mirapex caused compulsive behaviors was financial gain. Defendants weighed the impact of a gambling warning upon sales of Mirapex. For example, one document concludes that a "Compulsivity Label Change" would have a "Negative Impact on Mirapex Share and Growth" and represent a "Potential Deviation" from an "incremental sales/expenses" line that trended upward. Similarly, Defendants in another document compared the prevalence of compulsive side-effects at particular doses where Mirapex sales were greatest:

> [T]otal dose of 1.5 mg/day [and] below you don't see ob/comp behavior or sudden onset of sleep. This is low dose for monotherapy but effective dose for adjunct therapy where we get most of our business.

119. Defendants' fraudulent conduct also included manipulating the medical literature. Defendants shaped the medical literature about Mirapex, such that the literature cannot accurately reflect Mirapex's dangers. According to the Standard Operating Procedure governing publications, Boehringer entities were required to develop a "publication strategy" for each project. The purpose of this strategy was not to disseminate important data to the medical community, but to "generate a consistent image of the drug." To this goal, Boehringer shaped the medical literature in order to 1) serve marketing needs of showing effectiveness and 2) downplay dangers of the drug. Boehringer's policy was to ghost write draft publications which later surfaced as supposed objective medical literature. Alarmingly, Boehringer hired a group to draft articles. Articles were also drafted or outlined by a public relations firm, often before a medical author was even identified. The articles were then sent to the "client," either "Pfizer medical" or "BI medical and mktg" who made changes. Only then were the articles sent to the person whom would ultimately be listed as the author.

120. Defendants manipulated literature on the very issues in this case. One publication considered by Boehringer's Mirapex Publication Strategy was an article on "gambling" by a doctor who was once head of the Parkinson's Disease Foundation. The Publication Strategy establishes that in a "Pub Plan Meeting [publication planning meeting] held on June 8, 2004, Boehringer "agreed to offer assistance" to the doctor. The reason for BI's willingness to assist was very self-serving, and undercuts the objectivity of any ultimate article: "BI agreed to offer assistance in development [of the article on gambling] **to manage message."**

121. Defendants also exercised veto and editing powers by restricting researchers' ability to publish data without prior approval. The question of whether data developed in clinical trials would be published was controlled by Defendants:

> Prior to publication of any results pertaining to the clinical trial, the investigator must submit a copy of the manuscript, abstract, etc. to the medical monitor who will circulate the materials for review and approval according to the Upjohn Manuscript/Abstract Publication Approval Process.

122. When negative data about Mirapex was published, such as the Mayo Clinic study showing that agonists (and in 9 of 11 cases, Mirapex) were "uniquely implicated" as a cause of pathological gambling, Defendant's consultants immediately challenged the data. On the other hand, when data seemed positive from Defendants' point of view, Defendants would facilitate its publication. For example, in May 2004, Defendants reviewed a doctor's advance manuscript regarding depression and treatment with dopamine agonists in Parkinson disease patients. The doctor reflected his understanding that the Defendants would help with publicity and further development of the research: "I am sending you the article that has been written . . . . If the article is accepted then we can discuss how best to publicize it . . . . [A]n option would be to expand the article into a book[.]

123. Defendants' willingness to help publish selected data apparently led to editing powers over what was portrayed as objective data. The doctor's abstract discussing "Gambling, Sex and Parkinson's Disease," was sent to both Pfizer and Boehringer scientists with the alarming instructions to "please feel free to make any changes." Similarly, Defendants inserted their own

conclusions into the medical literature, editing manuscripts of the CALM-PD data prior to its publication, and then wrongfully portrayed those conclusions in promotional pieces as objective scientific conclusions by medical scientists.

124. Defendants also fraudulently concealed and minimized, in their meetings with physicians, the fact that Mirapex causes compulsive behaviors. Defendants used purportedly positive data about Mirapex to deflect physicians' concerns about compulsive behaviors. The "Mirapex Objection Handler" instructs sales representatives who are asked about compulsive behavior side-effects to "Neutralize" the concern with a method called "Influence with off-setting benefit" by pointing to purportedly positive data This positive data, however, was not objective science.

125. At the time the aforesaid representation s were made by Defendants and at the time Plaintiff received Mirapex, Plaintiff and her physicians, and the public in general reasonably believed them to be true. At the time that Plaintiff received, Defendants failed to inform Plaintiff and her physicians, and the public in general reasonably believed them to be true. At the time that Plaintiff received, Defendants failed to inform Plaintiff or her prescribing doctor, Dr. Blankenship, that Mirapex caused compulsive behavior, including compulsive shopping, spending and gambling, despite Defendants being in possession of such evidence. Plaintiff received no warnings, either written or oral that Mirapex caused obsessive compulsion behavior, including compulsive gambling, shopping and spending and relied on these omissions. In reasonable and justified reliance upon said representations and omissions by Plaintiff and her physicians, Plaintiff purchased and ingested Mirapex, which she would have done but for Defendants' fraudulent concealment.,

126. As a direct and proximate result of reliance upon Defendants' misrepresentations and/or concealments, Plaintiff has suffered, and will continue to suffer physical injury, emotional distress, harm, and economic loss as alleged herein.

NINTH CAUSE OF ACTION
Violation of State Deceptive Acts and Practices, Unfair Trade Practices, Consumer Protection, Merchandising Practices, and False Advertising Acts

127. Plaintiff incorporates by reference all preceding paragraphs as if fully set set forth herein and further alleges as follows:

128. By reason of the conduct as alleged herein, and by inducing Plaintiff and her physicians to use Mirapex through the use of deception, fraud, false advertising, false pretenses, misrepresentations, unfair and/or deceptive practices and the concealment and suppression of material facts, including fraudulent statements, concealments and misrepresentations identified above and those which are incorporated by reference due to the limitations imposed by the Protective Order applicable in this case, Defendant violated the provisions of Minn. Stat. §§ 325F.67, 325F.69, 325D.13, and 325D.44, or, in the alternative, if the court finds that Minnesota law does not apply, New York General Business Law §§ 349, 350, 350(a), Conn. Gen. Stat. § 42-1 lO(b), and Tex. Bus. & Com. Code 17.46.

129. As a direct and proximate result of Defendants' statutory violations, Plaintiff used Mirapex, which she would not have done had Defendants not used deception, fraud, false advertising, false pretenses, misrepresentations, unfair and/or deceptive practices and the concealment and suppression of material facts to induce Plaintiff and her physicians to use Mirapex.

130. By reason of such violations and pursuant to Minn. Stat. § 8.31, subd. 3a, and §§ 32SD.44, 32SF.67, and 32SF.68-70, or, in the alternative, if the court finds that Minnesota law does not apply, New York General Business Law §§ 3SO(e), New York General Business Law §§ 349(h), Conn. Gen. Stat. § 42-llO(g), and Tex. Bus. & Com. Code 17.SO (2007), and for the public benefit, Plaintiff is entitled to seek compensatory damages, attorneys fees, injunctive and equitable relief, and other remedies as determined by the Court pursuant to Minn. Stat. § 8.31, subd. 3a, and §§ 32SD.44, 32SF.67, and 32SF.68-70, New York General Business Law §§ 350(e), New York General Business Law §§ 349(h), Conn. Gen. Stat. § 42-llO(g), and Tex. Bus. & Corn. Code 17.50 (2007).

TENTH CAUSE OF ACTION
Civil Conspiracy to Defraud

131. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

132. Defendants' fraudulent representations about Mirapex's causation of compulsive behaviors and material concealments about Mirapex and addiction, detailed above, were

motivated by community of purpose and/or a common understanding to defraud. Defendants worked in concert to accomplish the unlawful purpose of defrauding Plaintiff and/or pursued a lawful purpose by unlawful means.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff seeks judgment in favor as follows:

1. Awarding actual damages to Plaintiff incidental to the purchase and ingestion of Mirapex in an amount to be determined at trial;

2. Awarding the costs of treatment for Plaintiffs' injuries caused by Mirapex;

3. Awarding injunctive relief, including disgorgement of all profits made from and monies paid for Mirapex and an injunction prohibiting Defendants from making false and misleading statements about the safety of Mirapex;

4. Awarding damages for Plaintiffs' physical pain and suffering;

5. Awarding damages for Plaintiffs' mental and emotional anguish;

6. Awarding pre-judgment and post-judgment interest to Plaintiffs;

7. Awarding the costs and expenses of this litigation to Plaintiffs;

8. Awarding reasonable attorneys' fees and costs to Plaintiffs as provided by law;

9. Awarding punitive damages and other exemplary relief pursuant to the Order filed November 27, 2007, in *In re: Mirapex Products Liability Litigation*, MDL No. 1836; and

10. For such further relief as this Court deems necessary, just and proper including by not limited to, requiring Defendant to pay for a medical monitoring program and compelling Defendant to adequately warn consumers about the substantial risks associated with Mirapex.

JURY DEMAND

Plaintiff hereby requests a trial by jury, pursuant to Rule 3 of the Federal Rules of Civil Procedure, on all claims and issues so triable.

Dated: August 4, 2014

THE TUTTLE LAW FIRM

By:__________________________________

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